K 062326

510(k) Summary of Safety and Effectiveness

SEP - 1 2006

SUBMITTER:	United States Surgical, a division of Tyco Healthcare Group LP 150 Glover Avenue Norwalk, CT 06856 Tel. No.: (203) 845-1000
CONTACT PERSON:	Daniel Campion Associate, Regulatory Affairs
DATE PREPARED:	August 7, 2006
TRADE/PROPRIETARY NAME:	autosuture™ Modified VERSAPORT™ trocar with fixation sleeve
COMMON/USUAL NAME:	Surgical Trocar
CLASSIFICATION NAME:	Endoscope and Accessories
PREDICATE DEVICE(S):	autosuture™ VERSAPORT trocar, Ethicon Endopath™ III Dilating tip Trocar
DEVICE DESCRIPTION:	The autosuture™ Modified VERSAPORT™ trocar with fixation sleeve is available in 5 mm short length, 5 mm regular length, 11 mm regular length, 12 mm regular length, and 12 mm long length sizes. The autosuture™ Modified VERSAPORT™ trocar with fixation sleeve has a sharp linear blade with a spring-loaded locking shield. Upon entry into a free space the shield advances to cover the blade, reducing the potential for injury to internal structures. The trocar sleeve contains an internal seal to prevent loss of pneumoperitoneum when instruments are inserted or withdrawn. The VERSASEAL™ self-adjusting seal accommodates instruments ranging from 5 mm to 12 mm and is designed to effectively reduce the seal diameter to allow insertion of smaller instruments. There is a stopcock valve for insufflation and rapid desufflation.
INTENDED USE:	The autosuture™ Modified VERSAPORT™ trocar with fixation sleeve is intended for use in a variety of gynecologic, general, thoracic and urologic endoscopic procedures to create and maintain a port of entry.
TECHNOLOGICAL CHARACTERISTICS:	The autosuture™ Modified VERSAPORT™ is identical to the predicate devices in terms of its intended use. The device will now be offered with a fixation sleeve and beveled tip.
MATERIALS:	All components of the autosuture™ Modified VERSAPORT™ trocar with fixation sleeve are comprised of materials which are in accordance with ISO Standard 10993-1.
PERFORMANCE DATA:	In-vitro and in-vivo tests were performed to verify that the autosuture™ Modified VERSAPORT™ trocar with fixation sleeve is substantially equivalent to the predicate devices in

creation and maintaining a port of entry and to validate that the autosuture™ Modified VERSAPORT™ trocar with fixation sleeve will perform as intended.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP - 1 2006

United States Surgical
% Mr. Daniel Campion
Associate, Regulatory Affairs
150 Glover Avenue
Norwalk, Connecticut 06856

Re: K062326
Trade/Device Name: autosuture™ Modified VERSAPORT™ trocar with fixation sleeve
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: GCJ
Dated: August 8, 2006
Received: August 9, 2006

Dear Mr. Campion:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

for P Jok

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications For Use

510(k) Number (if known): K062326

Device Name: **autosuture™ Modified VERSAPORT™ trocar with fixation sleeve**

Indications For Use:

The autosuture™ Modified VERSAPORT™ trocar with fixation sleeve is intended for use in a variety of gynecologic, general, thoracic and urologic endoscopic procedures to create and maintain a port of entry.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

PCH

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K062326